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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Robert Graham Urie

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EXAMINER

LLOYD, EMILY M

ART UNIT

PAPER NUMBER

3736

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,893	Applicant(s) URIE, ROBERT GRAHAM	
	Examiner EMILY M. LLOYD	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-17, 19 and 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 18, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2011 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's 31 January 2011 amendment. The Examiner acknowledges Applicant's replacement drawing sheets 1-3/3 and the amendments to the abstract, specification, and claims 1, 18, 20 and 21. Currently, claims 1-25 are pending, and claims 11-17, 19 and 22-25 are withdrawn from prosecution.

Drawings

The amendment filed 31 January 2011 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the change in shape of the tapered end 46 of Figure 4 presents new matter, as this shape was not presented with Applicant's specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37

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CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

The Examiner further notes that Applicant need only provide replacement sheet(s) and annotated sheet(s) for sheet(s) that are amended.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 18, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 states "a proximal end the stiffness being defined as the force required to produce an angular lateral displacement, distal to the applied force, of 30 degrees when applied at a distance of 10 mm from the distal end of the respective length of guidewire, with the proximal end of the guidewire being laterally constrained." The Examiner notes that Applicant's specification does not teach that the proximal end of the guidewire is laterally constrained. (The Examiner notes that the specification appears mute to constraining/holding/securing the guidewire at all, let alone a particular portion of the guidewire.) Further, Applicant's specification does not teach that the

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applied force is "at a distance of 10 mm from the distal end of the respective length of guidewire." As such, these limitations were not described in the application, as filed, in a manner that indicated that Applicant had possession of them at the time of filing.

Claims 2-10, 18, 20 and 21 are rejected as ultimately depending on or incorporating claim 1.

Claims 1-10, 18, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 states "A guidewire... comprising: *a proximal end* having a stiffness greater than 10 N *the stiffness being defined as the force* required to produce an angular lateral displacement, distal to the applied force, of 30 degrees when *applied at a distance of 10 mm from the distal end of the respective length of guidewire, with the proximal end of the guidewire being laterally constrained.*" (emphasis added). In Applicant's claim 1, the proximal end of the guidewire is laterally constrained. However, the stiffness is defined by applying a force "10 mm from the distal end of the respective length" and measuring a displacement distal to the applied force; the Examiner notes that for the proximal end, this force would be applied to the "laterally constrained" proximal end of the guidewire. As the proximal end is laterally constrained, it is unclear how any force would result in a distal angular displacement. As such, Applicant has not

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enabled one of ordinary skill in the art at the time the invention was made to make or use the invention, as one of ordinary skill in the art could not measure a proximal end of the guidewire in the manner claimed. Claims 2-10, 18, 20 and 21 are rejected as ultimately depending on or incorporating claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 18, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states "the stiffness being defined as the force required to produce an angular lateral displacement, distal to the applied force, of 30 degrees when applied at a distance of 10 mm from the distal end of the respective length of guidewire, with the proximal end of the guidewire being laterally constrained." The Examiner notes that it is unclear if the force is intended to have a particular direction with respect to the guidewire. The Examiner also notes that it is unclear if the angular displacement is measured over any portion of the guidewire distal to the applied force (including the distal end when the proximal end is being measured), is measured at "the distal end of the respective length of guidewire", over the entirety of the guidewire that is not constrained and/or another interpretation. Further, it is unclear how the stiffness of the proximal end can be measured when the proximal end is laterally constrained and yet stiffness is defined by applying a force "10 mm from the distal end of the respective

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length" and measuring a displacement distal to the applied force; the Examiner again notes that for the proximal end, this force would be applied to the "laterally constrained" proximal end of the guidewire. As the proximal end is laterally constrained, it is unclear how any force would result in a distal angular displacement; as such, it is unclear if Applicant intended to claim a different definition of stiffness, a different portion of the guidewire being laterally constrained, and/or another interpretation. Claims 2-10, 18, 20 and 21 are rejected as ultimately depending on or incorporating claim 1.

Regarding claim 20, it is unclear what structural limitations this intended use adds to the limitations of claim 1. It is unclear if the guidewire of claim 1, as presented, has a stiffness adapted to do this function; if so, this claim would not further limit claim 1.

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

A claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 18 is rejected under 35 USC 112, fourth paragraph, as being an improper dependent claim for failing to include all the limitations of the claim upon which it depends and/or for failing to further limit the subject matter of the claim upon which it depends.

Regarding claim 18, "the distal end extends over a length of at least 2 cm" does not include the limitation of claim 8 "the distal end extends over a length of between 2 and 8 cm", as "at least 2 cm" is broader than "between 2 and 8 cm".

Response to Arguments

Applicant's arguments filed 31 January 2011 have been fully considered but they are not persuasive.

The Examiner notes that, as discussed in the 35 USC 112 second paragraph rejections above, Applicant's amended claims are not clear. Regarding claim 20, the Examiner notes that Applicant did not address if the functional language of claim 20 further limited claim 1.

Regarding Applicant's argument that the present guidewire "exhibits an approximate stiffness of around 52 g/mm at the distal end and around 173.3 g/mm at the proximal end (see page 6, line 21 to page 8, line 2)" (page 11 of Applicant's 31 January 2011 amendment), the Examiner notes that it is unclear how Applicant converted their claimed stiffness measurement (measured in Newtons) to that of the prior art (measured in grams/mm). The Examiner notes that Applicant's specification, including the cited portion, does not disclose this conversion. The Examiner further notes that it is unclear how Applicant's measurement (in Newtons and using a length of 10 mm and an angle of 30 degrees) can be converted to the prior art's measurement (in grams/mm), as they each have different units. The Examiner notes that the numerical values of Applicant's claim (3 N and 10 N) correlate to the numerical values of Applicant's approximation (52 g/mm and 173.3 g/mm) in a ratio of 0.0577 (as $3/52$ and $10/173.3$ both equal 0.0577). As such, the Examiner further notes that it is unclear if

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Applicant's stiffness also correlates in such a straightforward manner to other measurements of stiffness that would be more commonly used in the prior art.

Regarding the prior art rejections, the Examiner notes that as Applicant's claims are drawn to measuring the proximal end stiffness in a manner that appears to be impossible, the prior art of record cannot be reasonably applied. However, reconsideration of the prior art of record will occur when Applicant's claims are clear enough that prior art can be reasonably considered and applied as appropriate. Further, regarding Applicant's arguments regarding the prior art, as Applicant has argued but not shown that Applicant's guidewire "exhibits an approximate stiffness of around 52 g/mm at the distal end and around 173.3 g/mm at the proximal end (see page 6, line 21 to page 8, line 2)" (page 11 of Applicant's 31 January 2011 amendment), the Examiner notes that the record is not clear how Applicant obtained their asserted approximate stiffness values in g/mm. However, should Applicant provide evidence (e.g. calculations) showing that their claimed stiffnesses are equivalent to the values argued, the Examiner notes that this will be considered when reevaluating the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

/EML/

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Supervisory Patent Examiner, Art Unit 3736